IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

INDIVIOR INC. and INDIVIOR UK LIMITED, Plaintiffs, v. TEVA PHARMACEUTICALS USA, INC., Defendant.	Civil Action No. 1:17-cv-7115

I. COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Indivior Inc. (formerly known as Reckitt Benckiser Pharmaceuticals Inc.) ("Indivior") and Indivior UK Limited (formerly known as RB Pharmaceuticals Limited) ("Indivior UK"), (collectively, "Plaintiffs") file this Complaint against Defendant Teva Pharmaceuticals USA, Inc. ("Teva" or "Defendant") and allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the Food and Drug Laws and Patent Laws of the United States, Titles 21 and 35 of the United States Code, respectively, arising from Teva's submission of a New Drug Application ("NDA") to the Food and Drug Administration ("FDA") seeking approval to manufacture, use, and sell a generic version of Plaintiffs' Suboxone® sublingual film prior to the expiration of United States Patent No. 9,687,454 ("the '454 patent" or "the patent-in-suit").

THE PARTIES

2. Plaintiff Indivior is a Delaware corporation having a principal place of business at 10710 Midlothian Turnpike, Suite 430, Richmond, Virginia.

3. Plaintiff Indivior UK Limited is a United Kingdom corporation having a principal place of business at 103-105 Bath Road, Slough, UK.

4. On information and belief, Teva Pharmaceuticals USA, Inc. is a Delaware corporation having a principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454.

JURISDICTION AND VENUE

5. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

6. On information and belief, Defendant is in the business of, *inter alia*, developing, manufacturing, obtaining regulatory approval, marketing, selling, and distributing generic copies of branded pharmaceutical products in New Jersey and throughout the United States.

7. The Court has personal jurisdiction over Teva USA by virtue of, *inter alia,* its systematic and continuous contacts with the State of New Jersey. On information and belief, Teva USA is registered to do business in the State of New Jersey under entity ID No. 0100250184. In addition, on information and belief, Teva USA has appointed a registered agent for service of process in New Jersey (Corporate Creations Network Inc., 811 Church Road #105, Cherry Hill, NJ 08002).

8. On information and belief, Teva USA holds licenses in the State of New Jersey as a "wholesaler" and "manufacturer and wholesaler" of drugs, with License Nos. 5003436 and 5000583, respectively. On information and belief, Teva USA employs people throughout the State of New Jersey, including at least the following two locations: 8 Gloria Ln, Fairfield, NJ 07004 and 208 Passaic Ave, Fairfield, NJ 07004. On information and belief, Teva USA conducts business in this Judicial District and purposefully avails itself of this forum by, among other things, making, shipping, using, offering to sell or selling, or causing others to use, offer to sell, or sell, pharmaceutical products in the State of New Jersey and deriving revenue from such activities. Also, on information and belief, Teva USA has customers in the State of New Jersey.

9. On information and belief, Teva USA has been sued for patent infringement in this Judicial District and did not contest personal jurisdiction in this Judicial District in at least the following cases: *Amarin Pharma, Inc., et al. v. Teva Pharmaceuticals USA, Inc.*, Civil Action No. 14-3558, *Boehringer Ingelheim Pharma GmBH & Co. KG, et al. v. Teva Pharmaceuticals USA, Inc., et al.*, Civil Action No. 14-7811, *Helsinn Healthcare S.A., et al., v. Teva Pharmaceuticals USA, Inc., et al.*, Civil Action No. 14-6341, *Novo Nordisk Inc., et al., v. Teva Pharmaceuticals USA, Inc.*, Civil Action No. 14-4248, *Otsuka Pharmaceutical Co., Ltd. v. Teva Pharmaceuticals USA, Inc., et al.*, Civil Action No. 14-5878, *United Therapeutics Corp. v. Teva Pharmaceuticals USA, Inc.*, Civil Action No. 14-5498, *AstraZeneca Pharmaceuticals LP v. Teva Pharmaceuticals USA, Inc. et al.*, Civil Action No. 15-7889, *Vivus, Inc. v. Teva Pharmaceuticals USA, Inc.*, Civil Action No. 15-6957, and *Adapt Pharma Operations Limited et al. v. Teva Pharmaceuticals USA Inc. et al.*, Civil Action No. 17-cv-05100. Further, on information and belief, Teva USA has purposefully availed itself of the benefits of this forum by filing counterclaims in each of those actions. Additionally, on information and belief, Teva USA has availed itself of this forum by bringing civil actions for patent infringement in this forum in at least the following cases: *Teva Pharmaceuticals USA, Inc., et al. v. Dr. Reddy's Laboratories, Ltd., et al.* Civil Action No. 14-471 and *Teva Pharmaceuticals USA, Inc., et al. v. Synthon Pharmaceuticals, Inc., et al.*, Civil Action No. 15-472.

10. Venue is proper in this District under 28 U.S.C. §§ 1391 and 1400.

THE PATENT-IN-SUIT

11. Plaintiff Indivior UK is the lawful owner of the '454 patent, and Plaintiff Indivior is an exclusive licensee of the '454 patent. The '454 patent, entitled "Sublingual and Buccal Film Compositions," was duly and legally issued on June 27, 2017, naming Garry L. Myers, Samuel

D. Hilbert, Bill J. Boone, Beuford Arlie Bogue, Pradeep Sanghvi, and Madhusudan Hariharan as inventors. A true copy of the '454 patent is attached hereto as Exhibit A.

SUBOXONE ® SUBLINGUAL FILM

12. Plaintiff Indivior is the holder of New Drug Application ("NDA") No. 22-410 for Suboxone® (buprenorphine hydrochloride and naloxone hydrochloride) sublingual film.

13. On August 30, 2010, the FDA approved NDA No. 22-410 for the manufacture, marketing, and sale of Suboxone® sublingual film for the treatment of opioid dependence. Plaintiff Indivior has sold Suboxone® sublingual film under NDA No. 22-410 since its approval.

14. The '454 patent is listed in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") as covering Suboxone® sublingual film.

DEFENDANT'S INFRINGING GENERIC PRODUCT

15. Defendant submitted NDA No. 208042 to the FDA under 21 U.S.C. § 355(b)(2), seeking approval to engage in commercial manufacture, use, and/or sale of Defendant's generic product before expiration of the patent-in-suit.

16. NDA No. 208042 refers to and relies on Plaintiffs' NDA for Suboxone® sublingual film and purports to contain data showing bioequivalence of Defendant's generic product with Suboxone® sublingual film.

COUNT 1
Infringement of the '454 Patent Under 35 U.S.C. § 271(e)(2)

17. On information and belief, Teva's generic product is covered by one or more claims of the '454 patent.

18. By filing NDA No. 208042 under 21 U.S.C. § 355(b)(2) for the purposes of obtaining approval to engage in the commercial manufacture, use, and/or sale of Teva's generic

product prior to the expiration of the ’454 patent, Teva’s has committed an act of infringement of the ’454 patent under 35 U.S.C. § 271(e)(2).

19. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the FDA set the effective date of approval for NDA No. 208042 to be a date which is not any earlier than the expiration date of the ’454 patent, including any extensions of that date.

COUNT 2

Declaratory Judgment of Infringement of the ’454 Patent Under 35 U.S.C. § 271

20. On information and belief, unless enjoined by this Court, Defendant plans and intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Defendant’s generic product immediately following approval of NDA No. 208042.

21. On information and belief, Defendant’s commercial manufacture of Defendant’s generic product before the expiration of the ’454 patent would infringe one or more claims of the ’454 patent under 35 U.S.C. § 271.

22. The acts of infringement by Defendant set forth above will cause Plaintiffs irreparable harm for which they have no adequate remedy at law, and those acts will continue unless enjoined by this Court.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court enter:

A. A judgment that Teva has infringed the ’454 patent under 35 U.S.C. § 271(e)(2) by maintaining NDA No. 208042;

B. A declaratory judgment that Defendant’s commercial manufacture within the United States of Teva’s generic product would infringe the ’454 patent under 35 U.S.C. § 271;

C. Preliminary and permanent injunctions, restraining and enjoining Teva, its officers, agents, attorneys, affiliates, divisions, successors and employees, and those acting in privity or concert with them, from engaging in, causing, or inducing the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of drugs and formulations, or from inducing and/or encouraging the use of methods, claimed in the patent-in-suit;

D. An order that the effective date of any approval of NDA No. 208042 be a date that is not earlier than the expiration of the patent-in-suit, including any extensions thereof and any later expiration of exclusivity associated with the ’454 patent;

E. A judgment and order finding that this is an exceptional case within the meaning of 35 U.S.C. § 285 and awarding to Plaintiffs their reasonable attorneys’ fees;

F. A judgment granting Plaintiffs compensatory damages in an amount to be determined at trial including both pre-judgment and post-judgment interest if Teva commercially manufactures, uses, offers to sell, or sells in the United States, or imports into the United States, Teva’s generic product before the expiration of the patent-in-suit, including any extensions; and

G. Any and all other relief as the Court deems just and proper.

Dated: September 14, 2017

TROUTMAN SANDERS LLP

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